

National Comprehensive  
Cancer Network<sup>®</sup>

# Breast Cancer Screening and Diagnosis Guidelines

Version 1.2002

Continue

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**Clinical Trials:** The NCCN believes that the best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

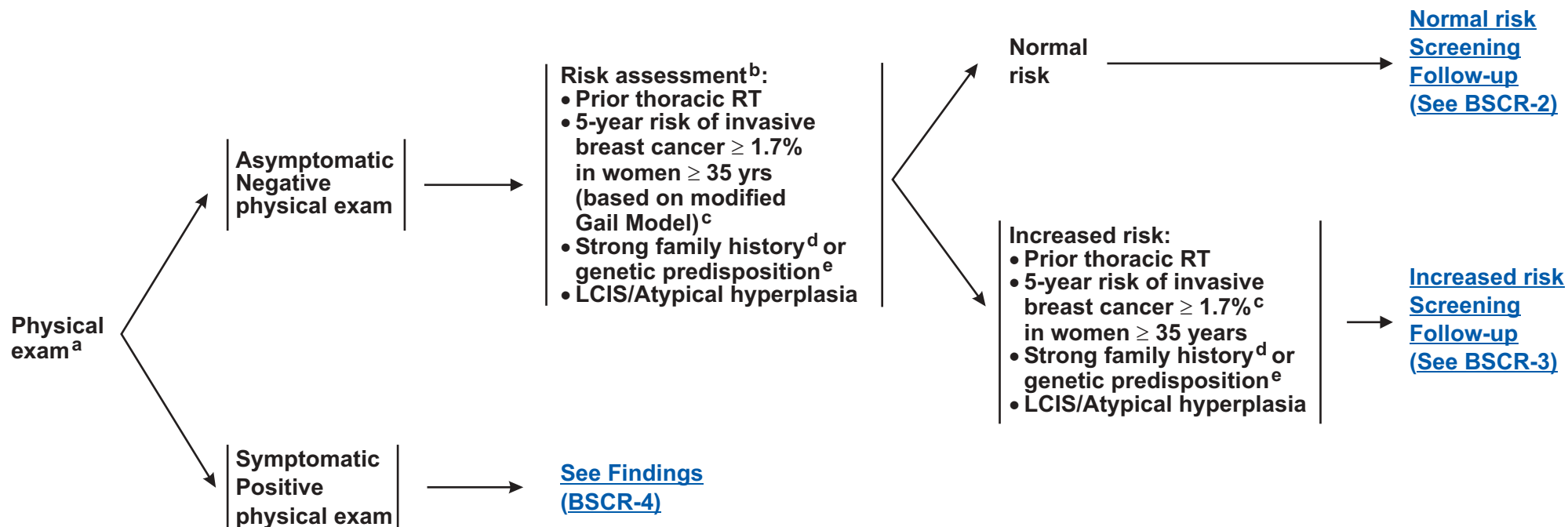
To find clinical trials online at NCCN member institutions, [click here: nccn.org/clinical\\_trials/physician.html](#)

**NCCN Categories of Consensus:** All recommendations are Category 2A unless otherwise specified.

See [NCCN Categories of Consensus](#)

These guidelines are a statement of consensus of the authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The National Comprehensive Cancer Network makes no representations nor warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way. These guidelines are copyrighted by National Comprehensive Cancer Network. All rights reserved. These guidelines and the illustrations herein may not be reproduced in any form without the express written permission of NCCN. ©2002.

SCREENING OR SYMPTOM CATEGORY



<sup>a</sup>See [Breast Screening Considerations \(BSCR-A\)](#).

<sup>b</sup>Refer to the [NCCN Breast Cancer Risk Reduction Guidelines](#) for a detailed qualitative and quantitative assessment.

<sup>c</sup>[Risk Factors Used in the Modified Gail Model \(BSCR-B\)](#).

<sup>d</sup>For a definition of strong family history, see [NCCN Genetics/Cancer Screening Guidelines](#).

<sup>e</sup>As currently defined in the American Society of Clinical Oncology Guidelines (Statement of the American Society of Clinical Oncology: Genetic testing for cancer susceptibility, adopted on February 20, 1996. J Clin Oncol 14(5):1730-1736, 1996.

[See NCCN Genetics/Cancer Screening Guidelines](#).

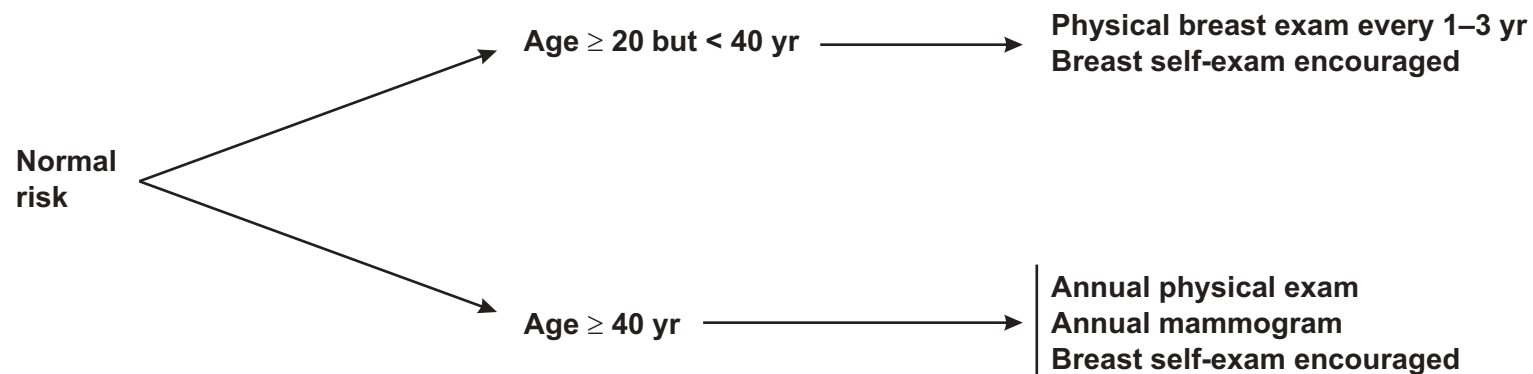
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BSCR-1

SCREENING OR SYMPTOM CATEGORY

SCREENING FOLLOW-UP<sup>a</sup>



<sup>a</sup>[See Breast Screening Considerations \(BSCR-A\).](#)

[Physical exam \(See BSCR-1\)](#)

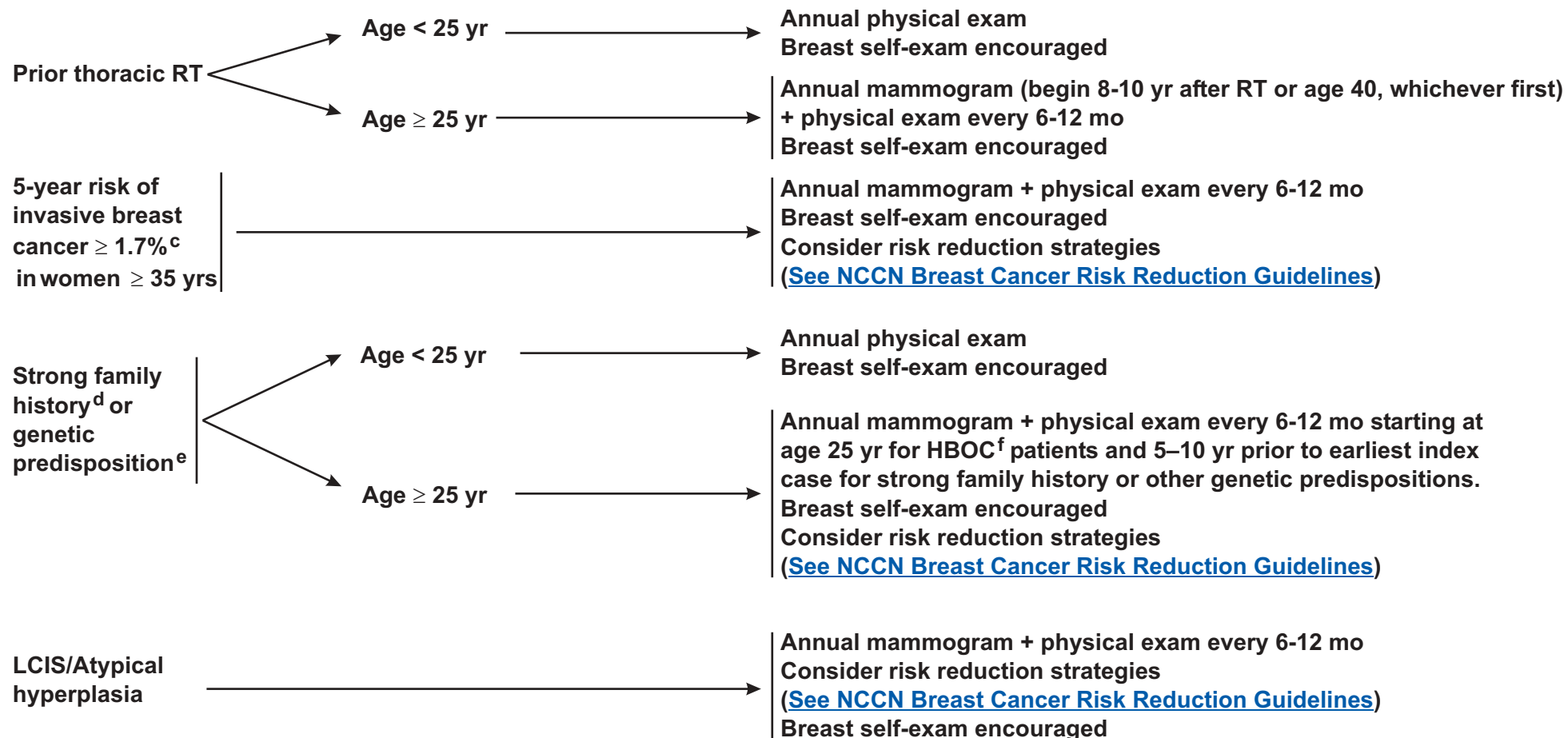
[Mammographic evaluation \(See BSCR-16\)](#)

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SCREENING OR SYMPTOM CATEGORY

SCREENING FOLLOW-UP



<sup>c</sup>[Risk Factors Used in the Modified Gail Model \(BSCR-B\).](#)

<sup>d</sup>For a definition of strong family history see [NCCN Genetics/Cancer Screening Guidelines](#).

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<sup>f</sup>[See NCCN Genetics/Cancer Screening Guidelines](#).

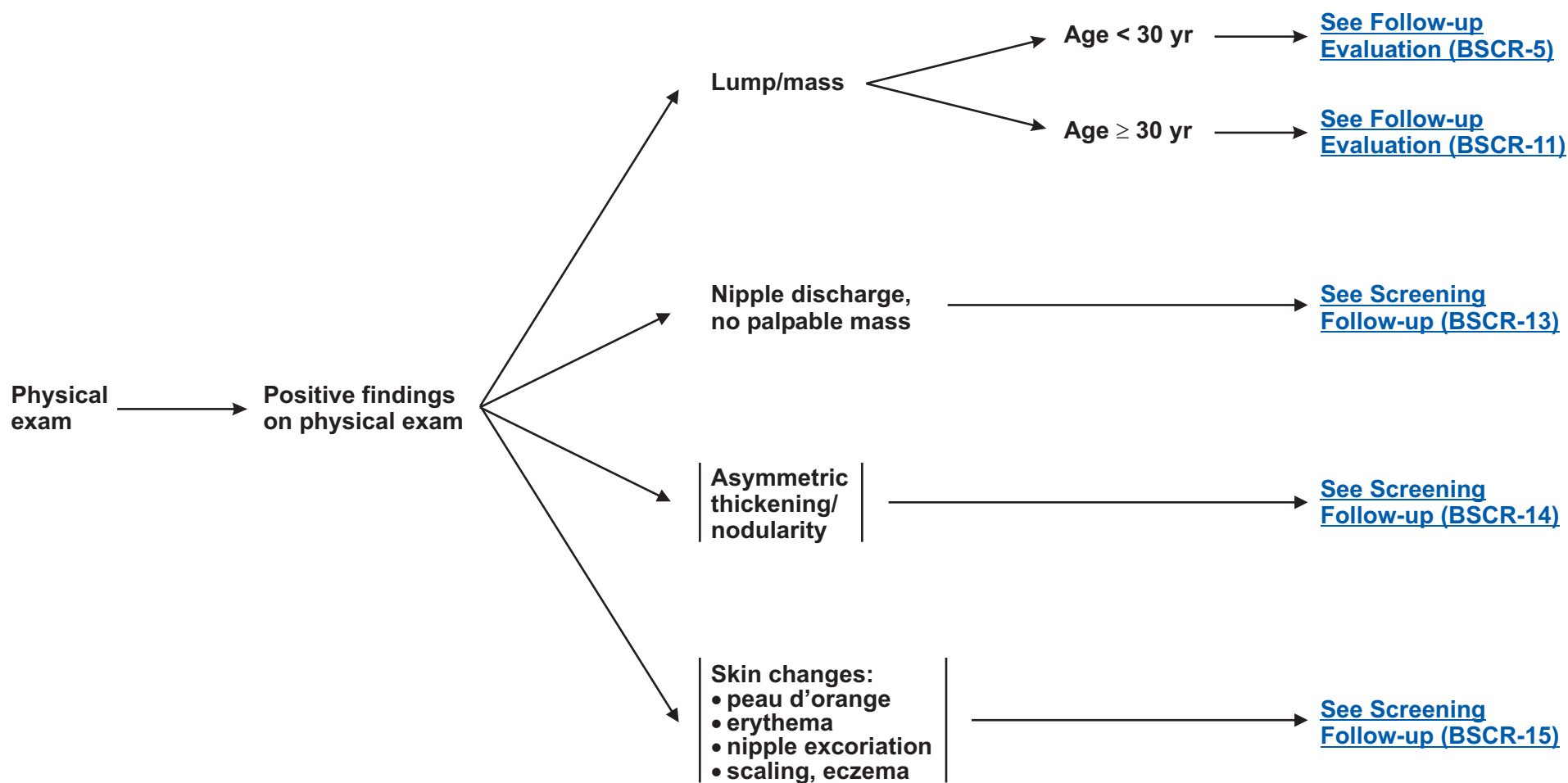
[Physical exam](#)  
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[Mammographic evaluation](#)  
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SCREENING OR SYMPTOM CATEGORY

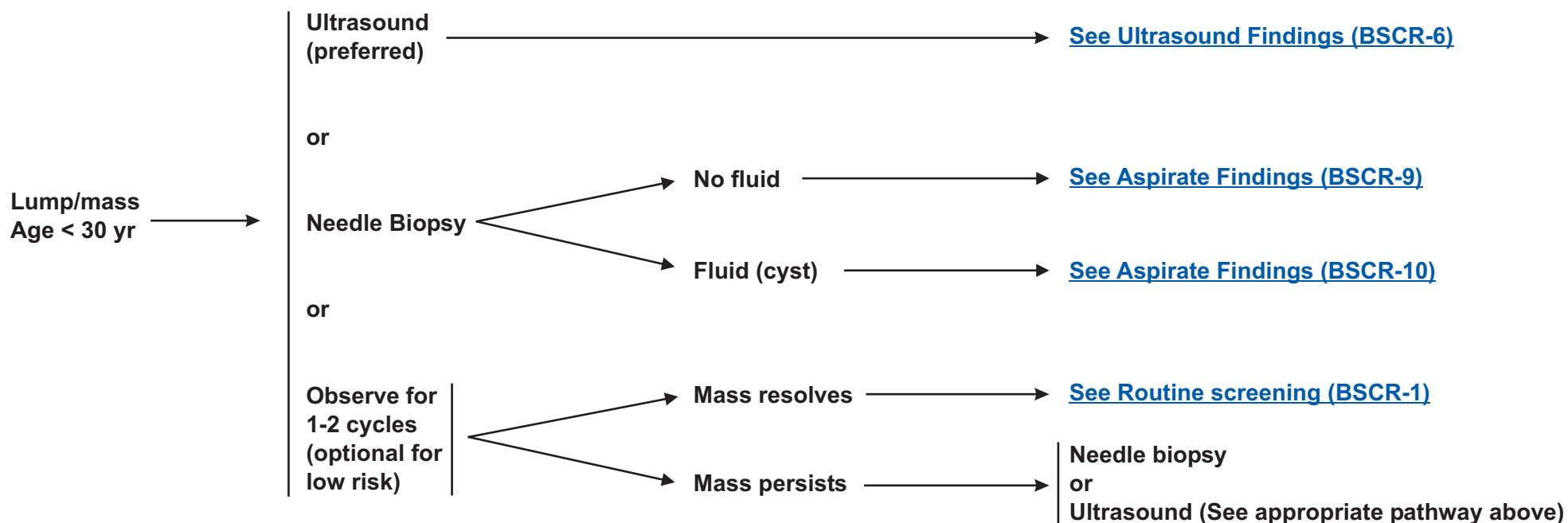


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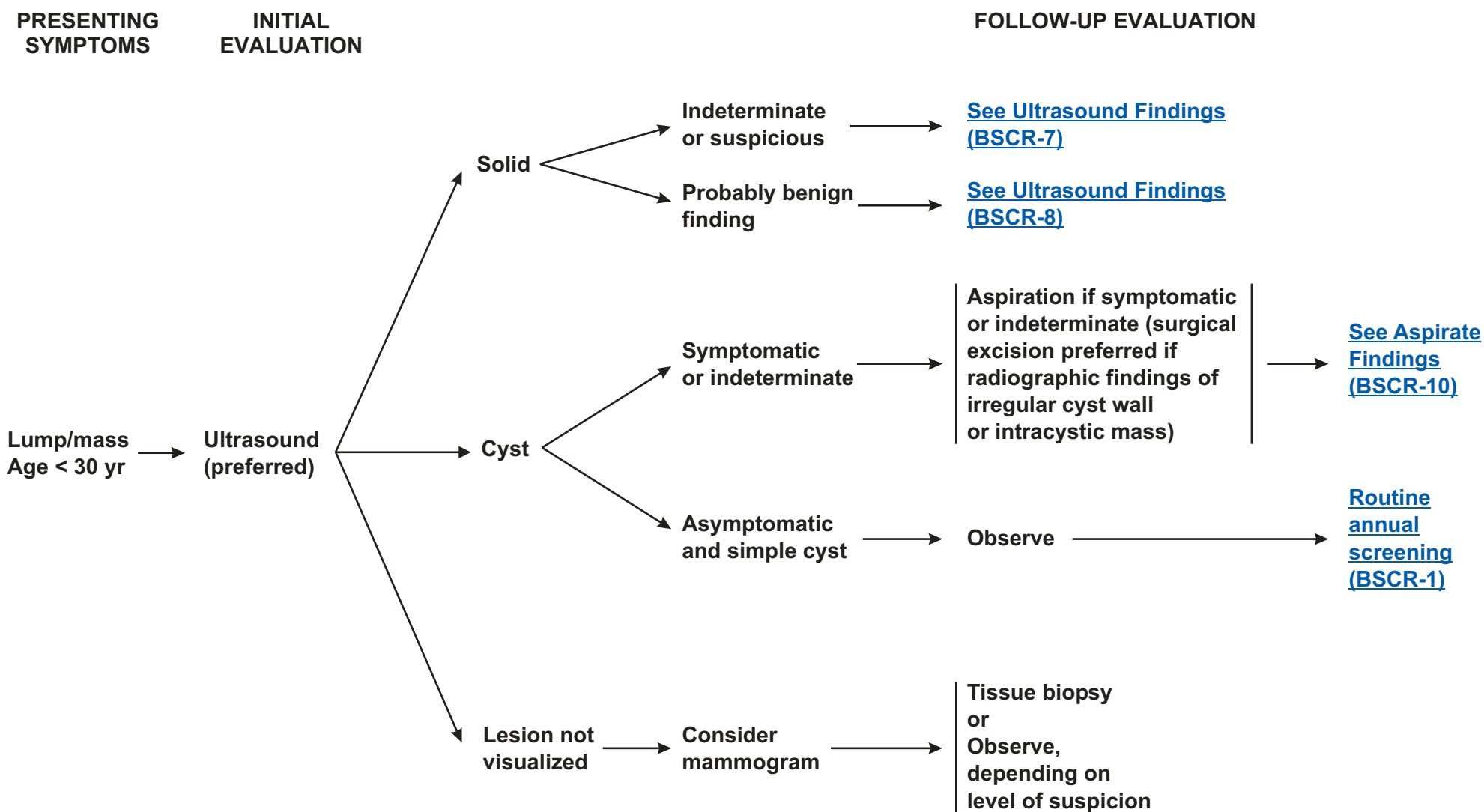
PRESENTING SYMPTOMS

INITIAL EVALUATION

FOLLOW-UP EVALUATION



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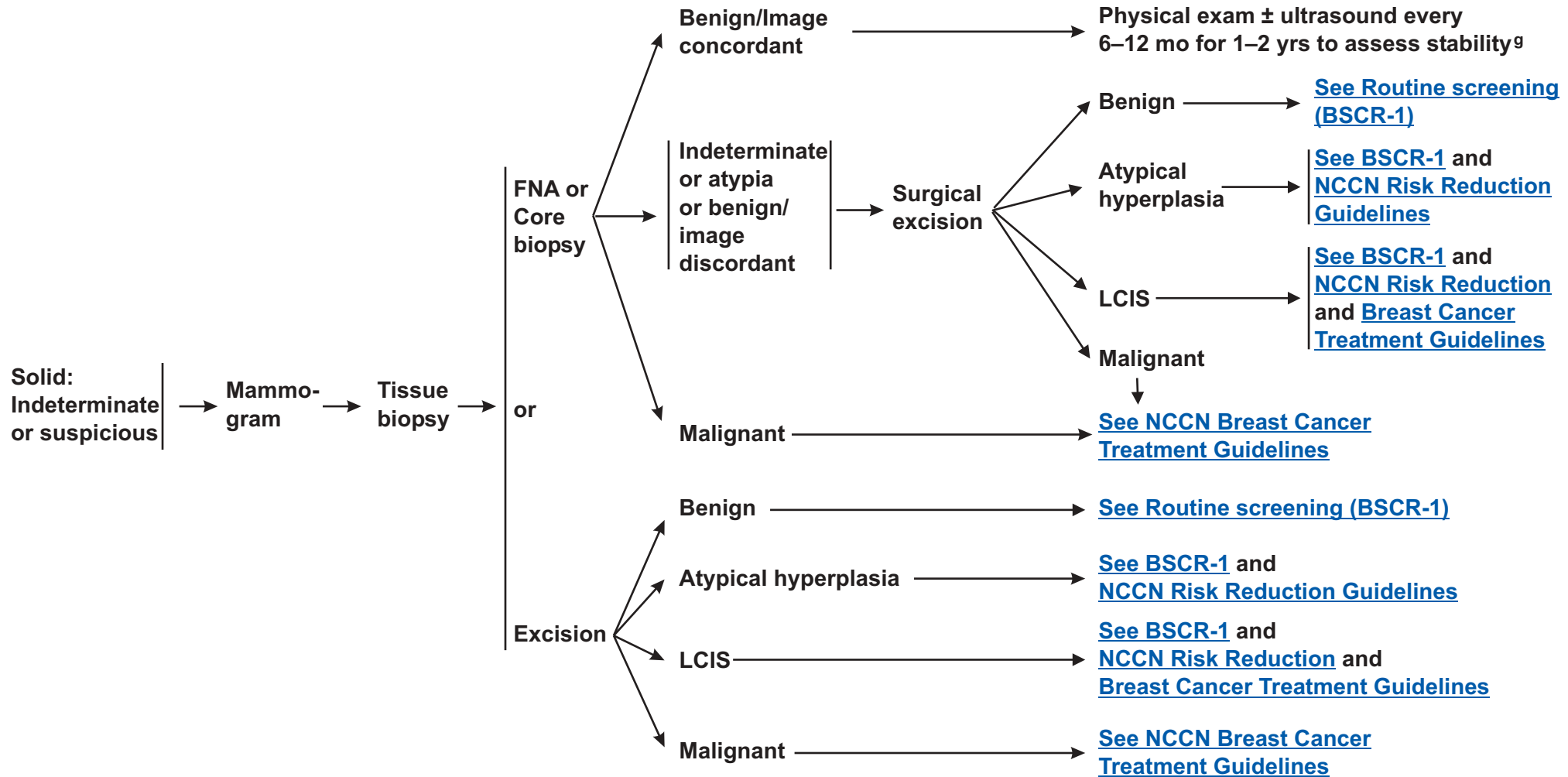
[Back to Lump/mass, Age < 30 yr, Initial Evaluation \(BSCR-5\)](#)

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ULTRASOUND FINDINGS  
LUMP/MASS

FOLLOW-UP EVALUATION



<sup>9</sup>Follow-up may be considered at earlier time intervals, if clinically indicated.

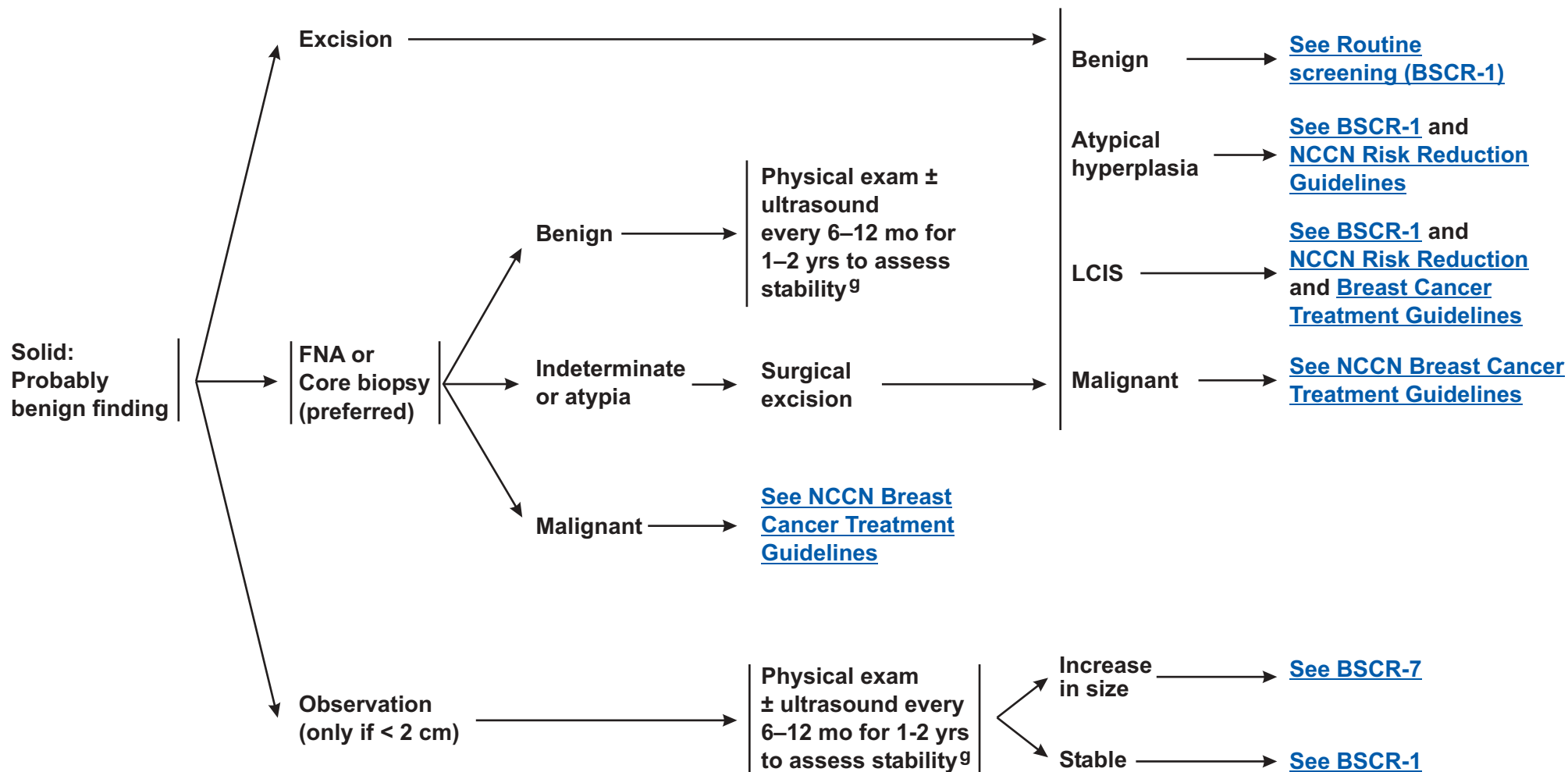
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ULTRASOUND FINDINGS  
LUMP/MASS

FOLLOW-UP EVALUATION



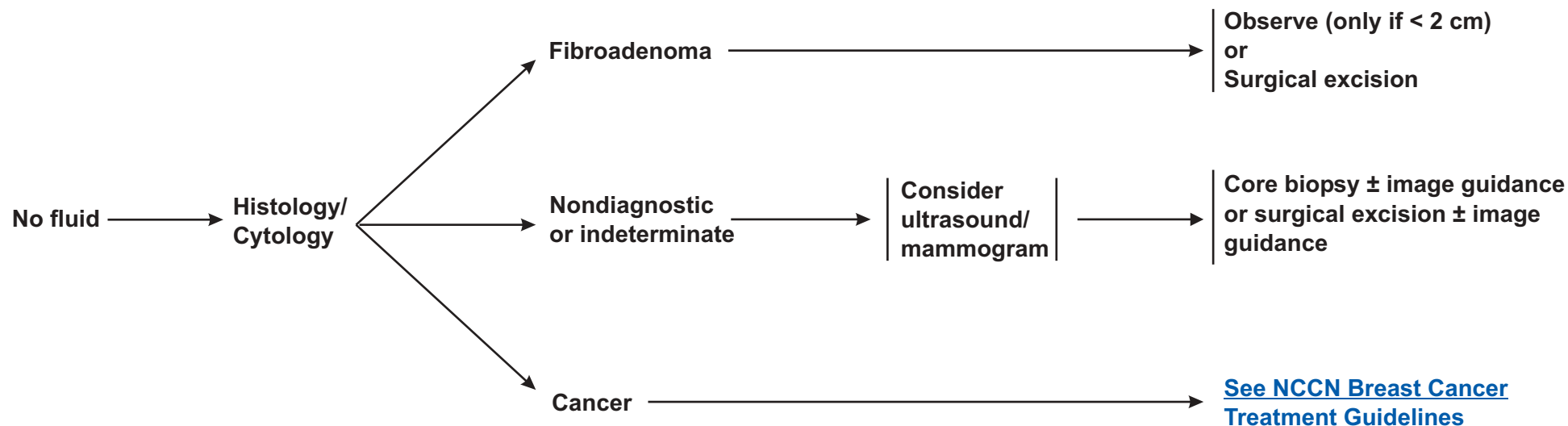
<sup>9</sup>Follow-up may be considered at earlier time intervals, if clinically indicated.

[See Breast Screening Table of Contents](#)

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**ASPIRATE FINDINGS**  
**LUMP/MASS, AGE < 30 YR**

**FOLLOW-UP EVALUATION**



[Back to Lump/mass,  
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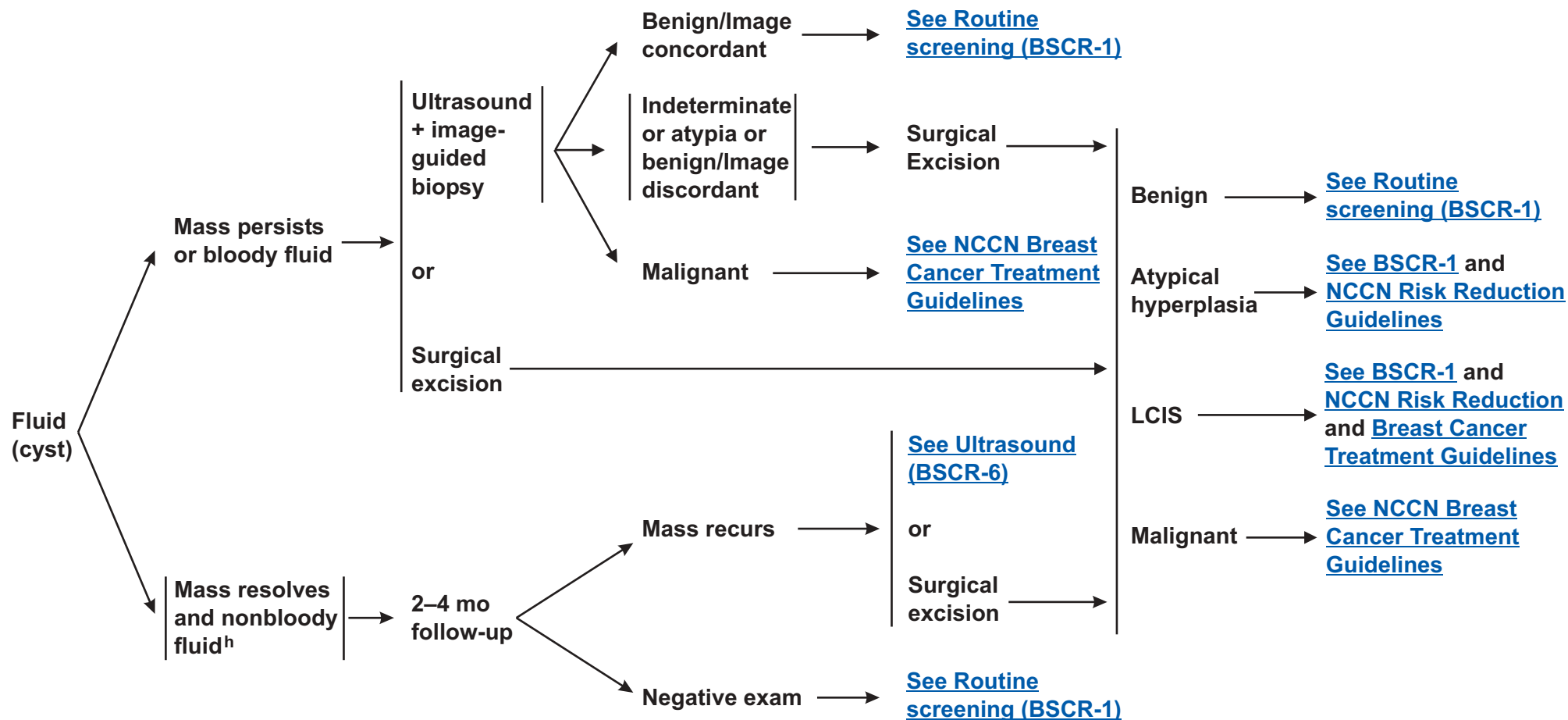
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**BSCR-9**

**ASPIRATE FINDINGS**  
**LUMP/MASS, AGE < 30 YR**

**FOLLOW-UP EVALUATION**



<sup>h</sup>Routine cytology not recommended.

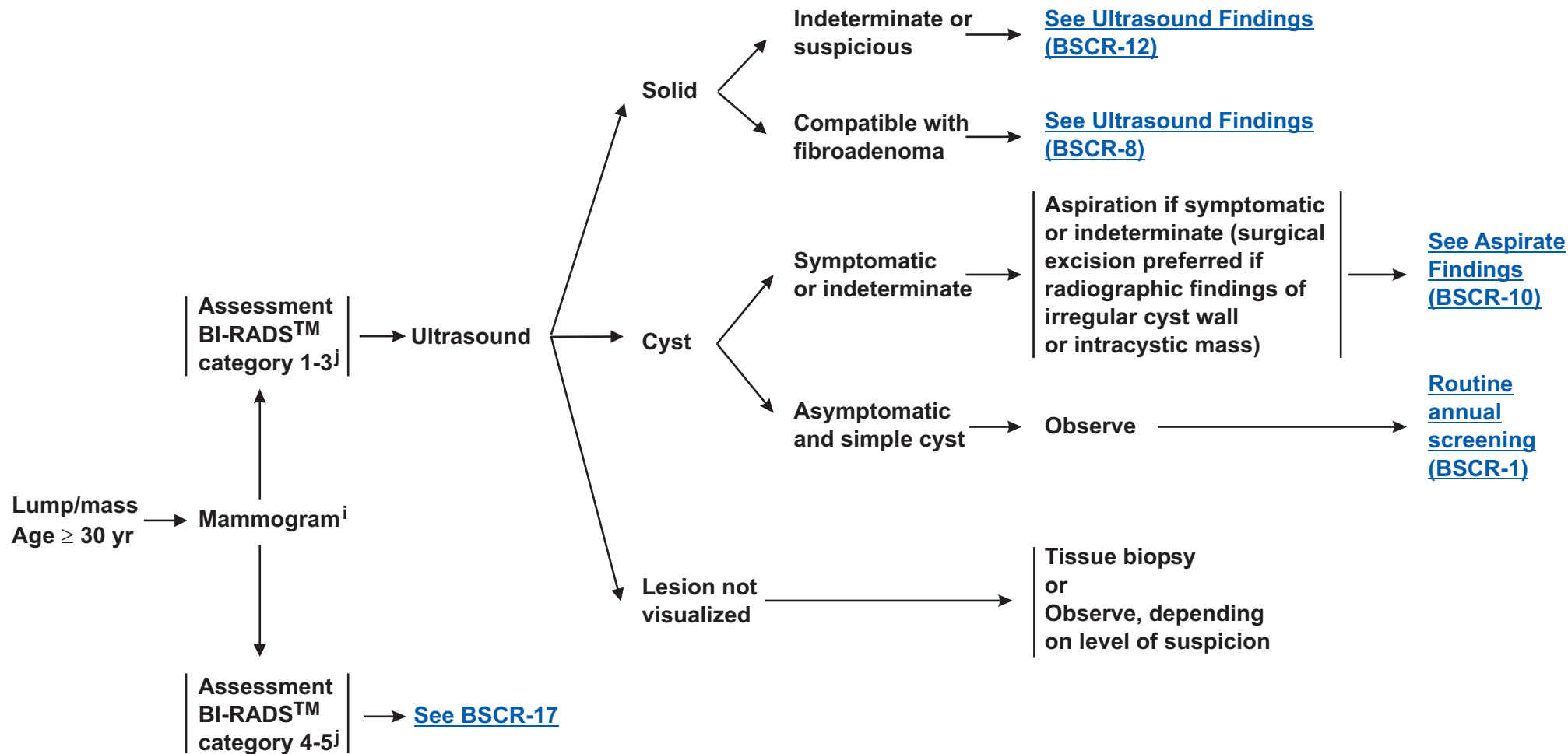
[Back to Lump/mass, Age < 30 yr, Initial Evaluation \(BSCR-5\)](#)

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PRESENTING SYMPTOMS

INITIAL EVALUATION

FOLLOW-UP EVALUATION



<sup>i</sup>There are a few clinical circumstances in which ultrasound would be preferred (eg, pregnancy and suspected simple cyst).

<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

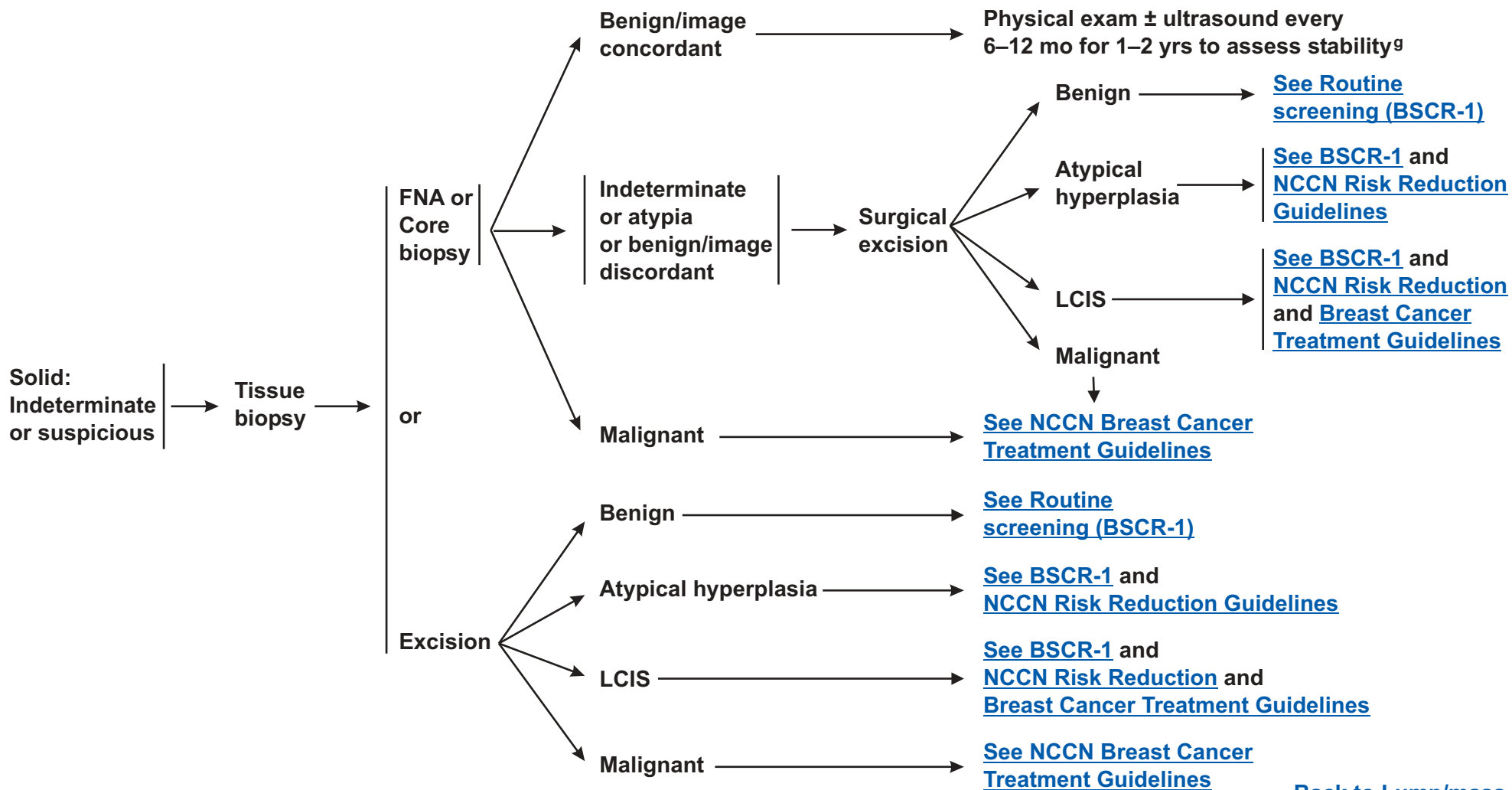
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ULTRASOUND FINDINGS

FOLLOW-UP EVALUATION

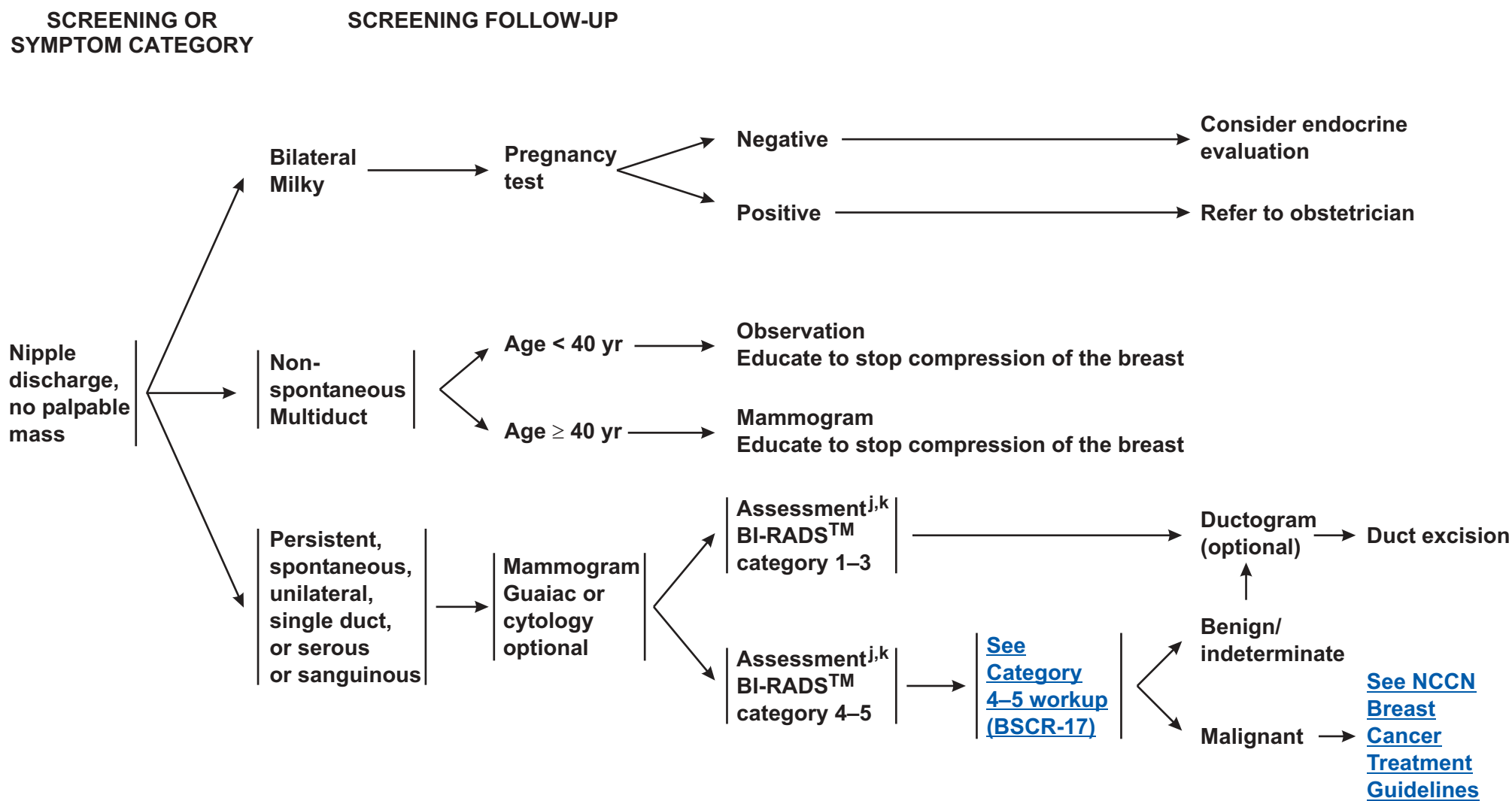


<sup>9</sup>Follow-up may be considered at earlier time intervals, if clinically indicated.

[Back to Lump/mass, Age ≥ 30 yr, Initial Evaluation \(BSCR-11\)](#)

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<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

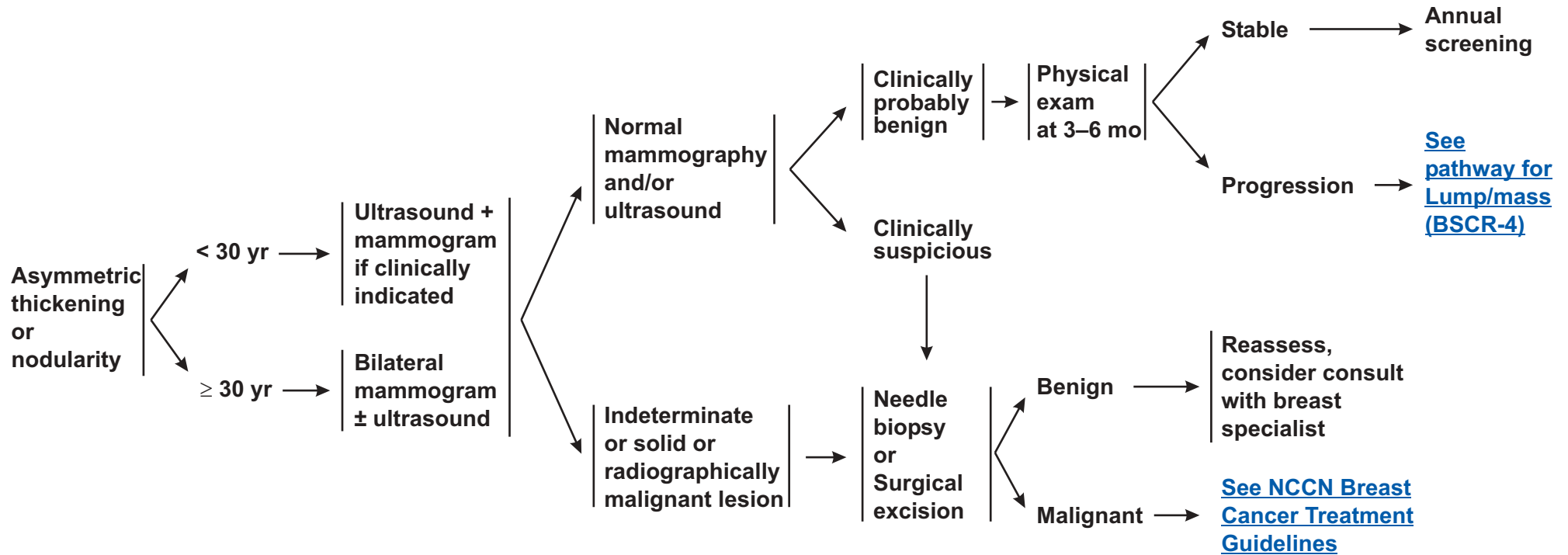
<sup>k</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988, 1997).

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SCREENING OR  
SYMPTOM CATEGORY

SCREENING FOLLOW-UP

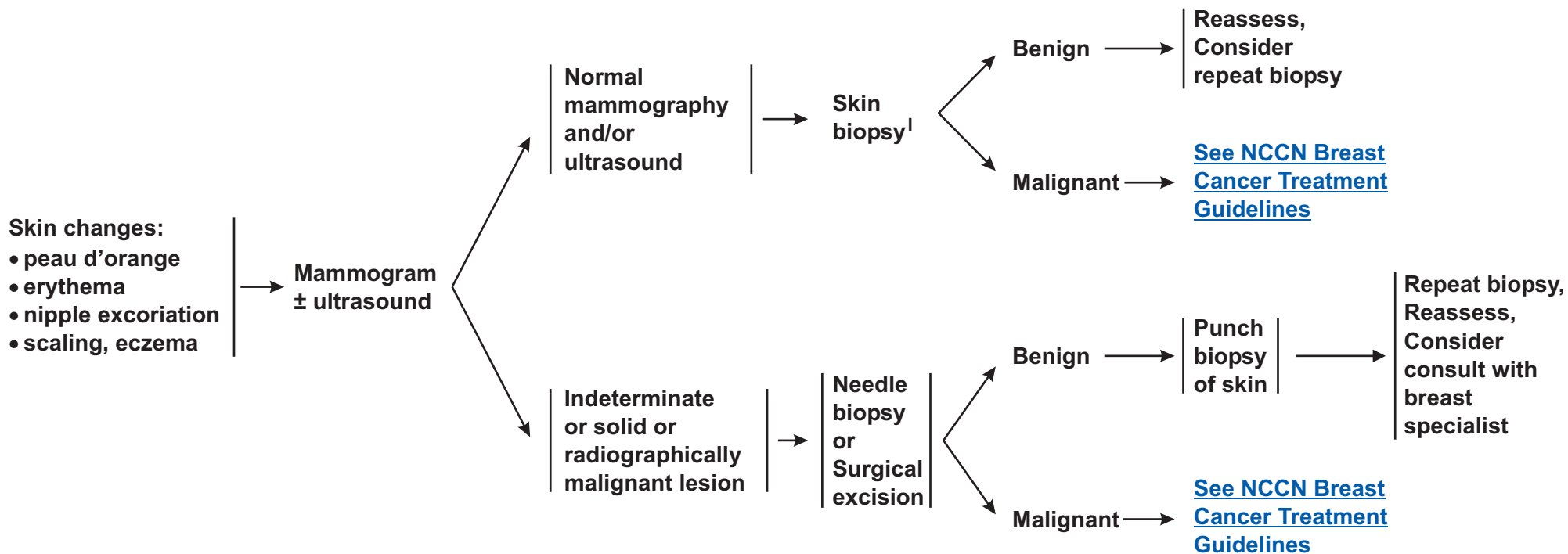


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SCREENING OR SYMPTOM CATEGORY

SCREENING FOLLOW-UP

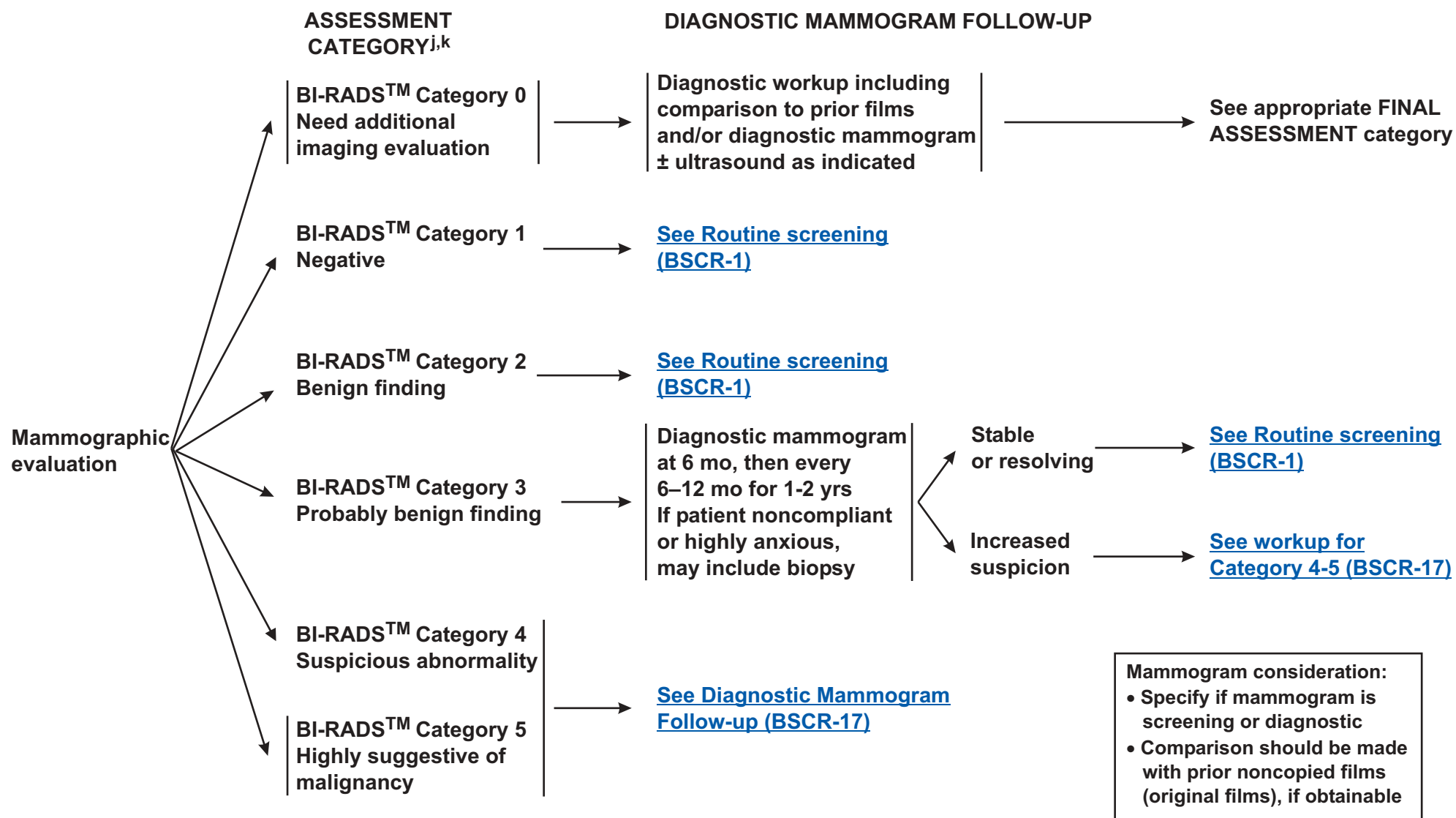


<sup>1</sup>If clinically of low suspicion, a short trial of antibiotics for mastitis may be indicated.

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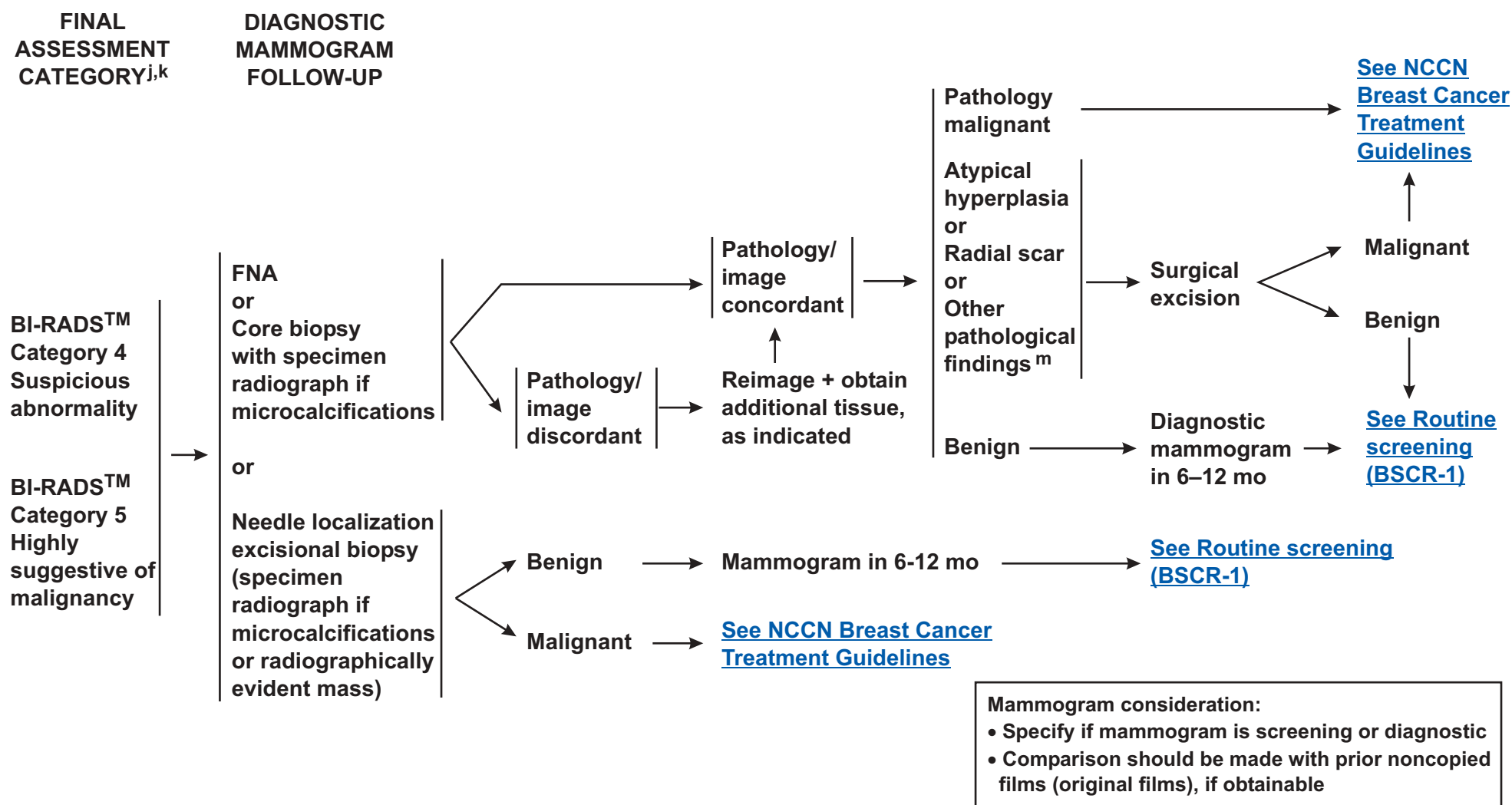


<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

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<sup>j</sup>See [Mammographic Assessment Category Definitions \(BSCR-C\)](#).

<sup>k</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. Federal Register 62(208):55988, 1997).

<sup>m</sup>Other histologies that may require additional tissue: mucin-producing lesions, potential phyllodes tumor, LCIS, other histologies of concern to pathologist.

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## BREAST SCREENING CONSIDERATIONS

- Consider severe comorbid conditions limiting life expectancy and whether therapeutic interventions are planned.
- Upper age limit for screening is not yet established.
- Breast self-exam is considered optional, because a survival benefit has not been proven; however, BSE may detect interval cancers between screenings and should be encouraged.
- Current evidence does not support the use of breast scintigraphy (e.g., sestamibi scan), ultrasound or MRI as screening procedures. The role of ductal lavage in breast screening is considered investigational.

[Back to Physical exam \(BSCR-1\)](#)

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**BSCR-A**

### RISK FACTORS USED IN THE MODIFIED GAIL MODEL<sup>n</sup>

- Current age
- Age at menarche
- Age at first live birth
- Number of first-degree relatives with breast cancer
- Number of previous benign breast biopsies
- Atypical hyperplasia in a previous breast biopsy
- Race<sup>o</sup>

For calculation of risk, based on the modified GAIL model, see [www.nci.nih.gov](http://www.nci.nih.gov).

<sup>n</sup>For detailed information, see [www.nci.nih.gov](http://www.nci.nih.gov).

<sup>o</sup>Current Gail Model is appropriate for non-Hispanic women. An updated version for Hispanic women is available at [www.nci.nih.gov](http://www.nci.nih.gov).

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**BSCR-B**

MAMMOGRAPHIC ASSESSMENT CATEGORY DEFINITIONS<sup>k,p</sup>**A. Assessment Is Incomplete:****Category 0- Need additional imaging evaluation:**

Finding for which additional evaluation is needed. This is almost always used in a screening situation and should rarely be used after a full imaging workup. A recommendation for additional imaging evaluation includes the use of spot compression, magnification, special mammographic views, ultrasound, aspiration, etc. The radiologist should use judgment in how vigorously to pursue previous studies.

**B. Assessment Is Complete - Final Categories:****Category 1: Negative:**

There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.

**Category 2: Benign Finding:**

This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galactoceles, and mixed-density hamartomas all have characteristic appearances, and may be labeled with confidence. The interpreter might wish to describe intramammary lymph nodes, implants, etc, while still concluding that there is no mammographic evidence of malignancy.

**Category 3: Probably Benign Finding - Short Interval Follow-Up Suggested:**

A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data are becoming available that shed light on the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.

**Category 4: Suspicious Abnormality - Biopsy Should Be Considered:**

These are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant probabilities should be cited so that the patient and her physician can make the decision on the ultimate course of action.

**Category 5: Highly Suggestive of Malignancy - Appropriate Action Should Be Taken:**

These lesions have a high probability of being cancer.

<sup>k</sup>Mammography results are mandated to be reported using Final Assessment categories (Mammography Quality Standards Act, Final Rule. *Federal Register* 62(208):55988, 1997).

<sup>p</sup>Terminology in this table is reflective of the American College of Radiology (ACR). Illustrated breast imaging reporting and data system (BI-RADS<sup>™</sup>). Third Edition. Reston [VA]: American College of Radiology, 1998. For more information, see [www.acr.org](http://www.acr.org).

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**BSCR-C**

## Manuscript

### NCCN Categories of Consensus

**Category 1:** There is uniform NCCN consensus, based on high-level evidence, that the recommendation is appropriate.

**Category 2A:** There is uniform NCCN consensus, based on lower-level evidence including clinical experience, that the recommendation is appropriate.

**Category 2B:** There is nonuniform NCCN consensus (but no major disagreement), based on lower-level evidence including clinical experience, that the recommendation is appropriate.

**Category 3:** There is major NCCN disagreement that the recommendation is appropriate.

**All recommendations are category 2A unless otherwise noted.**

### Overview

The lifetime risk of a woman developing breast cancer in the United States has stayed essentially the same over the past 5 years. One of 9 women are at risk based on a life expectancy of 85 years. In 2002, an estimated 205,000 new cases of breast cancer (203,500 women and 1,500 men) will be diagnosed in the United States. The good news is that mortality from breast cancer has dropped slightly; 40,000 deaths (39,600 women and 400 men) from breast cancer are predicted for 2002.<sup>1</sup> Some experts have attributed this decrease to mammographic screening.<sup>2</sup>

The key to a continued reduction in mortality is early detection and accurate diagnosis made in a cost-effective manner. Practice

guidelines developed by the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening Panel are designed to facilitate clinical decision making.

### Physical Examination

The starting point of these guidelines for screening and evaluating breast abnormalities is physical examination. The general public and health care providers need to be aware that mammography is not a stand-alone procedure. Neither the current technology of mammography nor its subsequent interpretation is foolproof. Clinical judgment is needed to ensure appropriate management. The patient's concerns and physical findings must be considered along with the radiographic and histologic assessment.

### Asymptomatic Women with Negative Physical Findings

If the physical examination is negative in an asymptomatic woman, the next decision point is based on risk stratification. Women can be stratified into two basic categories for the purpose of screening recommendations: those at normal risk and those at increased risk. The increased risk category consists of four groups: (1) women who have previously received therapeutic thoracic irradiation; (2) women with a 5-year risk of invasive breast carcinoma greater than or equal to 1.7%; (3) women with a strong family history or genetic predisposition; and (4) women with lobular carcinoma in situ (LCIS) or atypical hyperplasia.

Strictly speaking, breast self-examination (BSE) is considered optional in all risk groups because there are no conclusive data that it affects survival.<sup>3</sup> However, BSE may detect interval cancers between routine screenings and, therefore, should be encouraged.

**Women at Normal Risk**

For women between ages 20 and 39, a physical breast examination every 1 to 3 years is recommended, with BSE encouraged. For women ages 40 and older, annual physical breast examination and screening mammography are recommended, with BSE encouraged. This recommendation that women begin annual screening at age 40 is based on a consensus statement from the American Cancer Society. The National Cancer Institute also agreed that screening in this younger age group does decrease mortality from breast cancer.<sup>4</sup> Recent studies have reported a survival benefit in younger women (approximately 30%) that is equivalent to that seen in women over age 50.<sup>5</sup>

**Women at Increased Risk**

*Women Who Have Received Prior Thoracic Irradiation:* For women age 25 and older who have received prior thoracic irradiation, annual mammograms and a physical breast examination every 6 to 12 months are recommended. BSE is encouraged. For these patients mammogram screening is usually initiated 8 to 10 years after radiation exposure or at age 40, whichever comes first. For women younger than 25, an annual physical breast examination is recommended and BSE is encouraged.

Results from the Late Effects Study Group<sup>6</sup> indicate that women who received thoracic irradiation in their second or third decade of life have a 35% risk of developing breast cancer by the age of 40. The overall risk associated with prior thoracic irradiation at a young age is 75 times greater than the risk of breast cancer in the general population. Although there is a concern that the cumulative radiation exposure from mammography in a young woman may itself pose a risk for cancer, the benefit of early detection of breast cancer in this high-risk group would outweigh that potential side effect.<sup>7</sup>

*Women age 35 or older with a 5-Year Risk of Invasive Breast Carcinoma greater than or equal to 1.7%:* For women between the ages of 35 and 59, risk assessment tools are available to identify those women who are at increased risk. The National Cancer Institute has developed a computerized risk-assessment tool based on the modified Gail model<sup>8</sup> that performs accurate risk projections for women with a number of risk factors for breast cancer. The modified Gail model assesses the risk of invasive breast cancer as a function of age, menarche, age at first live birth, number of first-degree relatives with breast cancer, number of previous benign breast biopsies, atypical hyperplasia in a previous breast biopsy, and race. The tool calculates and prints 5-year and lifetime projected probabilities of developing invasive breast cancer and can be used to identify women who are at increased risk.

A projected 5-year risk of 1.7% for developing invasive breast cancer in women between the ages of 35 and 59 in the modified Gail model is based on the average age of 60 for women in the United States to develop breast cancer. The 5-year predicted risk of breast cancer required to enter the National Surgical Adjuvant Breast and Bowel Project (NSABP) prevention trial of tamoxifen versus placebo was at least 1.7%.

Copies of the National Cancer Institute's risk assessment tool can be obtained on computer disk by writing to: Breast Cancer Risk Assessment Tool, Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A03, 31 Center Drive MSC 2580, Bethesda, MD 20892-2580. Copies can also be requested by calling the Cancer Information Service at 1-800-4-CANCER or by visiting the National Cancer Institute's Web site at <http://www.cancer.gov>.

For women age 35 or older with a risk greater than or equal to 1.7%, physical examinations every 6 to 12 months and annual mammography are recommended, and BSE is encouraged. In addition, women in this group should be asked to consider chemoprevention in accordance with the NCCN Breast Cancer Risk Reduction Guidelines.

*Women With a Strong Family History or Genetic Predisposition:* Genetic predisposition is defined by the family history one would use to refer a patient for genetic testing. The criteria for genetic predisposition developed by the American Society of Clinical Oncology<sup>9</sup> are as follows:

- A family has more than two breast cancer cases and one or more cases of ovarian cancer diagnosed at any age.
- A family has more than three breast cancer cases diagnosed before the age of 50.
- A family has sister pairs in which one of the following combinations was diagnosed before the age of 50: two breast cancers, two ovarian cancers, or a breast and an ovarian cancer.

Annual mammography and physical breast examination are recommended every 6 to 12 months starting at age 25 for women who inherit the genetic risk of breast-ovarian carcinoma and 5 to 10 years prior to the earliest index case for women otherwise predisposed by family history. BSE is encouraged. Women in this group should be afforded the opportunity to consider chemoprevention in accordance with the NCCN Breast Cancer Risk Reduction Guidelines. Because male transmission and family size may limit the observed number of cases, women in families with an unusually early onset of breast cancer, particularly those families with bilateral disease, should also be considered at genetic risk.

Women younger than age 25 with strong family history or genetic predisposition should have an annual physical breast exam and be encouraged to perform BSE.

The risk from radiation exposure due to mammography in young women with an inherited cancer predisposition is unknown, and there is concern about whether this genetic factor may increase sensitivity to irradiation. The cumulative risk of breast cancer, however, may be as high as 19% by the age of 40 in women with BRCA1 mutations.<sup>10</sup> Because the overall risk of breast cancer in BRCA1 or BRCA2 mutation carriers is estimated to be 20-fold greater than in the general population, the benefit of screening may justify the radiation exposure. Positive findings on physical examinations would lead to further investigation of thickening, nodularity, or asymmetry; a dominant mass; nipple discharge; or skin changes.

*Women with LCIS or Atypical Hyperplasia:* LCIS, although not in itself considered to be a site of origin for cancer, is associated with a 10% to 15% increase in the lifetime risk of subsequent development of cancer in each breast. In women with proliferative breast disease, a pathologic diagnosis of atypical hyperplasia confers a four- to five-fold increased relative risk of developing breast cancer. For women with LCIS or atypical hyperplasia, an annual mammogram and physical examination every 6 to 12 months are recommended. These women should also be asked to consider chemoprevention as described in the NCCN Breast Cancer Risk Reduction Guidelines.

### Special Considerations

Clinicians should always use judgment when applying screening guidelines ([BSCR-A](#)). If a patient has severe comorbid conditions limiting her life expectancy and no intervention would occur based

on the screening findings, then the patient should not undergo screening.

A second consideration is the time interval of screening in women in the 40 to 49 age group. Even though there is agreement between the American Cancer Society and the National Cancer Institute on the benefit of breast cancer screening, the interval of screening remains controversial--whether or not mammograms should be performed every year or every 1 to 2 years. The NCCN Breast Cancer Screening Guidelines Panel elected to follow the American Cancer Society guidelines of yearly mammography, as mammograms can often detect a lesion 2 years before the lesion is discovered by physical breast examination. To reduce mortality from breast cancer, yearly screening may be more beneficial.

There are limited data regarding screening of elderly women, because most clinical trials for breast screening have used a cutoff age of 65 or 70. With the high incidence of breast cancer in the elderly population, the same screening guidelines used for women who are age 40 or older are recommended.

As mentioned earlier, a survival benefit for BSE has not yet been demonstrated. BSE should be encouraged, however, because it may detect interval cancers between screenings. Current evidence does not support the use of breast scintigraphy (e.g., sestamibi scan), magnetic resonance imaging (MRI), or ductal lavage as routine screening procedures.

### Mammographic Evaluation

If the results of a screening mammography are normal, the follow-up is routine screening. When screening mammography reveals an abnormal finding, the radiologist should attempt to obtain any prior mammograms. This is most important for lesions that are of low

suspicion mammographically. If, after a comparison of films, there is still a questionable area that is not clearly benign, then a diagnostic mammogram, with or without sonography, should be performed.

The decision tree is then based on the Breast Imaging Reporting and Data System (BI-RADS<sup>™</sup>) developed by the American College of Radiology.<sup>11</sup> The purpose of BI-RADS<sup>™</sup>, now referred to as Final Assessment Category Definitions, is to create a uniform system of reporting mammography results with a recommendation associated with each category.

A Final Assessment categorization of “incomplete assessment” refers to a finding for which additional evaluation is necessary. This category is almost always used in the context of a screening mammogram and should not be used after the patient has returned from a diagnostic mammogram workup or an ultrasound examination. Usually, the recommendation is for additional evaluation using spot compression, magnification views, or other views tailored to the question in that particular patient.

After the mammographic assessment is completed, the abnormality is placed in one of the following five Final Assessment categories:

1. *Negative*: This is a negative mammogram. For example, the screening mammogram shows a small area of questionable abnormality but, after the spot compression views are performed, the finding is considered completely normal and of no clinical concern.
2. *Benign Finding*: This is also a negative mammogram, but there may be an actual finding that a questionable area is benign. The typical case scenarios include benign-appearing calcifications, such as a calcifying fibroadenoma, an oil cyst, or a lipoma.

**3. Probably Benign Finding: Short-Interval Follow-up Suggested:**

This is a mammogram that is usually benign. Close monitoring of the finding is recommended to ensure its stability. The risk of malignancy is estimated to be less than 3%.

**4. Suspicious Abnormality: Biopsy Should Be Considered:** These lesions fall into the category of having some probability of being malignant but are not obviously malignant mammographically. The risk of malignancy is widely variable and is greater than for category 3 but less than for category 5.

**5. Highly Suggestive of Malignancy:** These lesions have a high probability of being a cancer. They include a spiculated mass or malignant-appearing pleomorphic calcifications.

For categories 1 and 2, in which the mammogram is completely normal or the finding is benign mammographically, the recommendation is routine screening mammography in 1 year.

For category 3 (probably benign), diagnostic mammograms every 6 to 12 months for 1 to 2 years are appropriate. At the first 6-month follow-up, a unilateral mammogram of the index breast is performed. The 12-month study would be bilateral in women ages 40 and older so that the contralateral breast is imaged at the appropriate yearly interval. Depending on the level of concern, the patient is then followed, either annually with bilateral mammograms or every 6 months for the breast in question, for a total of 2 years.

If the lesion remains stable or resolves mammographically, the patient resumes routine screening intervals for mammography. If, in any of the interval mammograms, the lesion increases in size or changes its benign characteristics, a biopsy is then performed. The exception to this approach of short-term follow-up is when the patient is noncompliant, is highly anxious, or has a strong family

history of breast cancer. In those cases, initial biopsy with histologic sampling may be a reasonable option.

For categories 4 and 5, tissue diagnosis is necessary. Whichever biopsy procedure is used--aspiration, core biopsy, or needle localization excisional biopsy--concordance between the pathology report and the imaging finding must be obtained.<sup>12,13</sup> For example, a negative fine-needle aspiration associated with a spiculated category 5 mass is discordant and clearly would not be an acceptable diagnosis. When the pathology and the imaging are discordant, the breast should be reimaged and additional tissue sampled or excised.

If the pathology is malignant, the patient should be managed according to the NCCN Breast Cancer Treatment Guidelines. If the pathology is benign and concordant with the mammogram risk of suspicion, the patient is followed mammographically and a new baseline mammogram is performed in 6 to 12 months, depending on institutional preferences, or the patient returns to routine screening. However, certain benign histologies diagnosed using needle biopsy, such as atypical ductal hyperplasia or a radial scar, require excisional biopsy because these lesions may have an associated malignant process and the benign diagnosis represents a sampling error.<sup>14-16</sup>

## Positive Findings on Physical Examination

### Dominant Mass in Breast

A dominant mass is a discrete lesion that can be readily identified during a clinical breast examination. The guidelines separate the evaluation of the dominant mass into two age groups: women younger than age 30 and women age 30 or older.

*Women younger than age 30:* Because the degree of suspicion in women who are under the age of 30 is low, observation of the mass for one or two menstrual cycles is an option. The threshold for biopsy will be lower for women at increased risk based on prior thoracic irradiation exposure, previous biopsy findings, or a family history of breast cancer, with or without genetic test results. The other options are to consider fine-needle aspiration or ultrasound (preferred).

If observation is elected and the mass resolves after one or two menstrual cycles, the patient may return to routine screening. If the mass persists, then fine-needle aspiration or ultrasound (preferred) should be performed.

The two outcomes of fine-needle aspiration are fluid or no fluid. If no fluid is obtained, a pathologist should evaluate the cellular aspirate. If the cytology is consistent with fibroadenoma, the indications for surgical excision are the patient's level of anxiety, immediate plans for pregnancy, or a history of the mass increasing in size, with the possible differential diagnosis of a phyllodes tumor. If the fibroadenoma is less than 2 cm, observation is also an option.

If the aspirate is nondiagnostic or indeterminate, the patient may have a mammogram and further histologic tissue sampling should be performed, either by reaspirating with consideration of ultrasound guidance or by core needle or surgical biopsy. If the histologic evaluation reveals cancer, the patient should be treated according to the NCCN Breast Cancer Treatment Guidelines.

If blood-free fluid is obtained on aspiration and the mass resolves, the patient should be reexamined in 2 to 4 months. If the physical examination remains negative, the patient returns to routine screening. If the mass persists or recurs, further evaluation is

required by ultrasound or surgical excision. If nontraumatic bloody fluid is obtained on initial aspiration or if the mass persists after aspiration, then sonography with image-guided biopsy or surgical excision is warranted.

The preferred option for evaluating a dominant mass is to proceed directly to ultrasound. If the ultrasound evaluation reveals the mass to be consistent with an asymptomatic simple cyst, observation without aspiration would be appropriate, unless the patient is symptomatic or desires intervention because of anxiety. If a symptomatic or indeterminate cyst is found, aspiration should be considered. With an irregular cyst wall or intracystic mass, surgical excision is preferred. If ultrasound indicates the solid lesion is suspicious or indeterminate, a diagnostic mammogram should be obtained prior to tissue biopsy. The tissue biopsy should be obtained by fine needle aspiration, core biopsy, or surgical excision.

If the pathology is benign and concordant with the ultrasound and physical examination, a physical examination at 6 months, with or without ultrasound, is recommended, followed by ultrasound every 6 to 12 months for 1 to 2 years to assess stability. Follow-up may be considered at earlier time intervals if clinically indicated. If the findings are indeterminate or show atypia or discordance, surgical excision should be performed. If the lesion is malignant, the patient is treated according to the NCCN Breast Cancer Treatment Guidelines.

If the solid lesion is compatible on ultrasound with a fibroadenoma, several options are available: surgical excision, needle biopsy, or observation. Surgical excision is based on the patient's level of anxiety, intended pregnancy in the near future, or a history of enlarging mass. If the lesion has been surgically excised and proven

to be benign, the patient undergoes routine screening. If the option of needle biopsy is elected, a physical examination at 6 months with or without ultrasound is recommended, followed by ultrasound every 6 to 12 months for 1 to 2 years to ensure that the lesion is stable. Observation may be elected only if the lesion is less than 2 cm, in which case a physical examination at 6 months with or without ultrasound is recommended, followed by ultrasound every 6 to 12 months for 1 to 2 years. Follow-up may be considered at earlier time intervals if clinically indicated.

If the lesion cannot be visualized with ultrasound, a mammogram should be considered, followed by observation or tissue biopsy, depending on the level of suspicion.

*Women age 30 or older:* The main difference in the guidelines for evaluating a dominant mass in women age 30 or older is the increased degree of suspicion of breast cancer. The initial evaluation begins with a bilateral diagnostic mammogram. Observation without further evaluation is not an option. After the mammographic assessment, the abnormality is placed in one of the five Final Assessment categories.

For Final Assessment categories 1, 2, and 3, the next step is to obtain an ultrasound. From this point, the decision tree for women age 30 or older is almost identical to the pathway for younger women. (The only difference is the need for a diagnostic mammogram, in some situations, for the younger women.) For Final Assessment categories 4 and 5, tissue diagnosis through aspiration, core biopsy, or needle localization excisional biopsy is necessary.

### **Nipple Discharge Without a Dominant Mass**

In patients with a nipple discharge but no dominant mass, an evaluation of the character of the nipple discharge is the first step. If

the nipple discharge is bilateral and milky, then pregnancy or an endocrine etiology must be considered. The appropriate follow-up of a nonspontaneous, multiple-duct discharge in women under age 40 is observation, coupled with education of the patient to stop compression of the breast, if appropriate. In women age 40 or older, screening mammography and a further workup based upon the Final Assessment category is recommended.

The most worrisome nipple discharge is one that is persistent, spontaneous, unilateral, and from a single nipple duct, especially if the discharge is serous, sanguinous, or serosanguinous. A guaiac test and cytology of the nipple discharge are optional, as a negative result should not stop further evaluation. Evaluation of this type of nipple discharge is based on the Final Assessment category of the diagnostic mammogram. If the diagnostic mammogram is Final Assessment category 1, 2, or 3, then a ductogram may be performed to guide the surgical excision.

Ductal excision is indicated for diagnosis of an abnormal nipple discharge, even if the ductogram is negative. However, the ductogram is useful to exclude multiple lesions and to localize the lesions prior to surgery. If the patient has a mammogram that is a Final Assessment category 4 or 5, then the workup should proceed based on the diagnostic mammogram findings. If the workup findings are negative, a ductogram is optional, but surgical duct excision would still be necessary. If the workup of a category 4 or 5 mammogram is positive, the patient should be treated according to the NCCN Breast Cancer Treatment Guidelines.

### **Asymmetric Thickening or Nodularity**

Thickening, nodularity, or asymmetry is distinct from a dominant mass in that the finding is ill-defined and often vague on physical

breast examination. If the patient is younger than age 30 and has no high risk factors, ultrasound evaluation is appropriate. A mammogram would be performed only if the physical finding were clinically suspicious. Diagnostic mammograms for this age range are fairly low in yield because of the density of the breast and low risk of breast cancer.

In women over the age of 30, bilateral diagnostic mammograms, with or without an ultrasound evaluation, should be obtained. If the breast imaging results are abnormal, assessment of the thickening, nodularity, or asymmetry should be performed as previously outlined for a mammographic abnormality.

If the mammogram and ultrasound findings are normal, the abnormality should be reexamined in 3 to 6 months. If the abnormality is stable, annual screening can be resumed. If a progressive change is noted, however, workup should proceed as for a dominant mass.

### **Skin Changes**

The initial evaluation begins with a bilateral diagnostic mammogram with or without ultrasound examination if uncomplicated mastitis has been excluded. If the mammogram is abnormal, the evaluation proceeds based on the mammogram findings. If the breast imaging results are normal, further workup is still needed.

A skin biopsy, either punch or incisional, should be performed. If the skin biopsy is malignant, the patient should be treated according to the NCCN Breast Cancer Treatment Guidelines. However, if the skin biopsy is benign, a repeat biopsy should be performed and consideration given to consultation with a breast specialist.

### **Summary**

The intent of these guidelines is to give health care providers a practical, consistent framework for screening and evaluating a spectrum of breast lesions. Clinical judgment should always be an important component of the optimal management of the patient.

If the physical breast examination, radiologic imaging, and pathologic findings are not concordant, the clinician should carefully reconsider the assessment of the patient's problem. Incorporating the patient into the health care team's decision-making empowers the patient to determine the level of breast cancer risk that is personally acceptable in the screening or follow-up recommendations.

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